K071088

M&M INDUSTRIES, INC.

ISO 9001:2000

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CHATTANOOGA, TN 37419
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FAX (423) 821-9017
EMAIL pails@mmcontainer.com
WEBSITE www.mmcontainer.com

3. SUMMARY OF SAFETY AND EFFECTIVENESS

JUL - 5 2007

A. SPONSOR IDENTIFICATION

M & M Industries, Inc.
316 Corporate Place
Chattanooga, TN 37419
Office: 423.821.3302
Toll Free: 800.331.5305
Fax: 423.821.9017

B. ESTABLISHMENT REGISTRATION NUMBER: 1065324

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854
estrin@yourFDAconsultant.com

Tel: (301) 279 -2899
Fax: (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: November 13, 2006

E. PROPRIETARY (TRADE) NAME: **Life Latch® Sharps & BioHazard Container**

F. COMMON NAME: Sharps collection and disposal system

G. CLASSIFICATION NAME: Accessory to needle, hypodermic, single lumen

H. REGULATION NUMBER: 21 CFR 880.5570

I. PROPOSED REGULATORY CLASS: Class 2

J. DEVICE PRODUCT CODE: 80 FMI

K. MEDICAL SPECIALTY: General Hospital

L. DESCRIPTION OF DEVICE

The **Life Latch® Sharps & BioHazard Container** is a round white high density polyethylene (HDPE)) container. It has a flexible handle that rests at the side when not in use. The top of the container has one inch ridges all around the top, which fit into a slot around the inside of the lid. The container is fitted with an insert that snaps into four slots on the container near the top. This insert has a three inch opening in the

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center. Emanating from that opening are slots that remind one of six slices of pie. This allows the opening to be enlarged when necessary to add a large sharps product. It is used as a safety feature to allow visual checking of the extent that the container is filled while discouraging hands from touching the sharps. The lid has a safety lever to help prevent accidental opening of the container.

M. INDICATIONS FOR USE:

The M & M Industries, Inc. **Life-Latch® Sharps & Biohazard Containers** are indicated for single use containment of medical waste, including, but not limited to, hypodermic needles, syringes, lancets, and blood needles. The containers can be used in a variety of health settings, such as hospitals, physician offices, dental offices, patient rooms, laboratories, home health and other generators of contaminated sharps or infectious waste.

N. PREDICATE DEVICE: Sage Products, Inc. Sharps Disposal Containers with Screw Top Caps (K980490).

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The **Life Latch® Sharps & BioHazard Container** are substantially equivalent products in all areas impacting safety and effectiveness and technological characteristics to Sage Products, Inc., sharps Disposal Containers with Screw Top Caps (K980490).

P. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

M & M Industries, Inc. **Life Latch® Sharps & BioHazard Container** production meets the following standards:

ASTM F2132-01 *Standard Specification for Puncture Resistance of Materials Used in containers for Discarded Medical Needles and Other Sharps, Direct Method.*

Department of Transportation (DOT) Title 49 CFR Section 178.603 (Impact Resistance).

The **Life Latch® Sharps & BioHazard Container** is certified in accordance with the requirements set forth in:

- U.N. Recommendations on the Transport of Dangerous Goods
- International Maritime Dangerous Goods (IMDG) Code
- International Civil Aviation Organization (ICAO) Technical Instructions
- International Air Transport Association (IATA) Dangerous Goods Regulations

Q. CONCLUSION

M & M Industries, Inc. **Life Latch® Sharps & BioHazard Container** meets appropriate standards and raises no safety/efficiency issues or claims that differ from the predicate device cited.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

M&M Industries, Incorporated
C/O Dr. Norman F. Estrin
President
Estrin Consulting Group, Incorporated
9109 Copenhaver Drive
Potomac, Maryland 20854

JUL - 5 2007

Re: K071088
Trade/Device Name: Life-Latch® Sharps & Biohazard Containers
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: June 11, 2007
Received: June 15, 2007

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

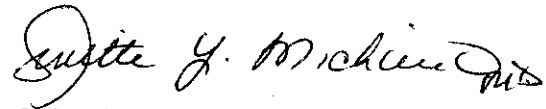
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CONFIDENTIAL

ATTACHMENT A

Indications for Use

510(k) Number (if known): K071088

Device Name: Life-Latch® Sharps & Biohazard Containers

Indications for Use:

The M & M Industries, Inc. Life-Latch® Sharps & Biohazard Containers are indicated for single use containment of medical waste, including, but not limited to, hypodermic needles, syringes, lancets, and blood needles. The containers can be used in a variety of health settings, such as hospitals, physician offices, dental offices, patient rooms, laboratories, home health and other generators of contaminated sharps or infectious waste. The sizes of containers that are the subject of this submission are the 3.5 gallon, 5.0 gallon and 6.5 gallon, in either white or black color.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K071088

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(Posted November 13, 2003) _____

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